

EFFICACY AND SAFETY OF MISOPROSTOL IN SECOND TRIMESTER MEDICAL TERMINATION OF PREGNANCY AT A TERTIARY LEVEL CENTRE IN KERALA

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ABSTRACT

BACKGROUND

Second trimester MTP is done by various methods. Most commonly used and studied in various regimens of Mifepristone and Misoprostol by oral and vaginal routes. FIGO recommended various regimens. In our institute, we have noted even lesser doses of drugs without prolongation of induction expulsion interval, patient responded well. Hence, we conducted this study.

MATERIALS AND METHODS

This non-randomised clinical trial of various doses of Misoprostol for second trimester MTP conducted at family welfare unit of Govt. Medical College, Kozhikode, from 1.1.2017 to 31.12.2017. Consecutive patients who satisfy inclusion criteria were divided into 3 groups. All A, B and C group took 600 mg Mifepristone orally and 200, 600 and 800 ug vaginal Misoprostol respectively. After 48 hrs., data was analysed by SPSS 16.0.

RESULTS

Majority of second trimester abortion were for anomalous babies (89%) and 11% were for medico-legal issues; 600 ug Misoprostol had 90% success rate.

CONCLUSION

600 mg Mifepristone followed by 600 ug Misoprostol had an induction expulsion interval of < 24 hrs. and equally efficacious too for the higher doses of Misoprostol regimens.

KEYWORDS

Mifepristone, Misoprostol.

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BACKGROUND

In developing countries like India, contraceptive methods are not widely practiced. In many cases either the pregnancy is unwanted because of social/ ethical reasons, lethal anomaly to the foetus and life-threatening condition for the women or failure of contraceptive.⁽¹⁾

Medical termination of pregnancy can be done through various regimens.⁽²⁾ Most commonly used and studied regimen includes that of mifepristone (antiprogestone) and misoprostol (Synthetic 15-deoxy-16-hydroxy-16-methyl analogue of PGE1).⁽³⁾ Misoprostol, being much cheaper, safe and capable of being easily stored at room temperature has been tried by both oral and vaginal routes in different dosage regimens with varying degrees of success.⁽⁴⁾ Oral misoprostol is associated with faster achievement of peak levels, but the effect lasts for less time and it is also associated with more side effects. However, vaginal route is associated with slower peak level achievement, but the effect lasts longer with fewer

side effects 3 - 5. We have used the vaginal route in our study.^(5,6)

FIGO in 2017 came out with a recommendation on the various dosage regimens for MTP.^(7,8) In our institution we have noticed that at even lesser doses of drugs, without undue prolongation of the induction expulsion interval patients respond well. Hence, we have conducted this study to look into the various regimens and to establish their efficacy.

Aim

To study the efficacy and safety of various regimens of intravaginal misoprostol in Second Trimester Pregnancy Termination.

Objectives

1. To compare efficacy of various doses of misoprostol used for Second Trimester Medical Termination Regimens.
2. To compare safety of various doses of misoprostol used for Second Trimester Termination of Pregnancy.
3. To identify common indications for Second Trimester Termination Pregnancy.
4. To find out various types of anomalies as indication for second Trimester Termination of Pregnancy.

MATERIALS AND METHODS

This Non-Randomised Clinical Trial of various doses of misoprostol for 2nd Trimester Termination of Pregnancy at Family Welfare Unit of Government Medical College, Kozhikode, was conducted from 1st January of 2017 to 31st

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December 2017 (1 year). Women between the ages of 18 - 42 years with 10 - 20 weeks of pregnancy requesting second trimester termination of pregnancy at Family Welfare Unit of Government Medical College, Kozhikode.

The Sample Size and Allocation of Study Subjects were taken for Convenience and was divided into Three Groups A, B and C-

Group A: Subjects receiving 600 mg oral mifepristone and 200 µg vaginal misoprostol.

Group B: Subjects receiving 600 mg oral mifepristone and 600 µg vaginal misoprostol.

Group C: Subjects receiving 600 mg oral mifepristone and 800 µg vaginal misoprostol.

Inclusion Criteria

- Indication for termination were in consonance with MTP Act 1971.
- Singleton pregnancy.
- Hb > 8 gm%.

Methodology

Group A: 600 mg mifepristone orally in empty stomach followed by 200 µg misoprostol after 48 hrs. by vaginal application.

Group B: 600 mg mifepristone orally in empty stomach followed by 600 µg misoprostol after 48 hrs. by vaginal application.

Group C: 600 mg mifepristone orally in empty stomach followed by 800 µg misoprostol after 48 hrs. by vaginal application.

If failure to expel within 24 hours was noted, misoprostol was repeated up to a maximum of 3 doses of 400 µg. Women’s vital signs were monitored. The progress of abortion was assessed by vaginal examination during administration of each dose.

Information about side effects was collected from each woman including nausea, vomiting, diarrhoea, fever, excessive bleeding and procedure related complications were noted.

All the women were kept in hospital after expulsion for 24 hrs. under observation. Indications for MTP and common anomalies leading to medical termination of pregnancy were noted. On discharge, patients were asked to come for follow-up after 4 weeks. On follow-up, general examination and pelvic examination were conducted and information regarding abnormal bleeding, discharge p/v or any other delayed side effects was collected.

Statistical Analysis

Data was analysed by using SPSS 16.0. Data was expressed as frequencies and percentages. Statistical analysis was done using chi-square tests. A ‘p’ value < 0.05 was considered to indicate statistical significance.

RESULTS

Majority (42%) of the patients were between 20 - 25 years of age and 60% patients were multiparous.

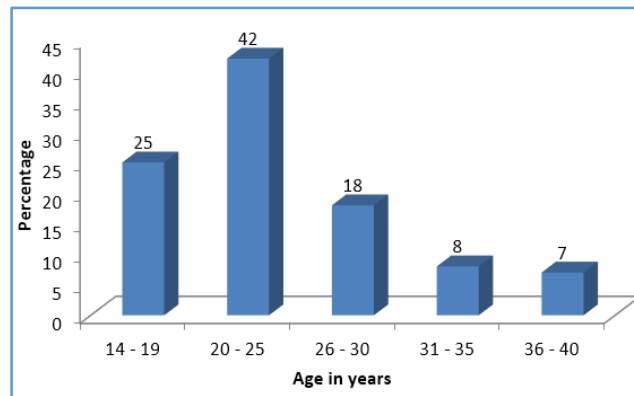


Figure 1. Age-Wise distribution of Patients

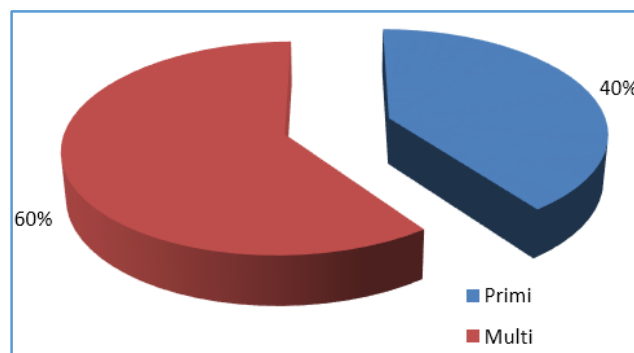


Figure 2. Parity-Wise distribution of the Patients

50% of terminations were between 18 - 20 weeks of gestational age.

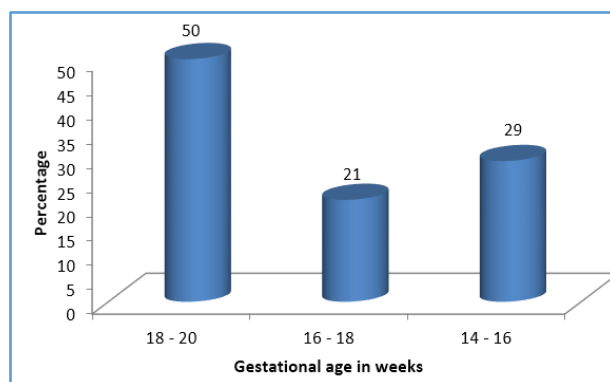


Figure 3. Gestational Age at Termination

600 mg mifepristone and 600 µg misoprostol has 90% success compared to 200 µg and 800 µg misoprostol, though it was not statistically significant.

Group	Success	Failure	P value
A	13 (65%)	7 (35%)	0.15
B	18 (90%)	2 (10%)	
C	14 (70%)	6 (30%)	

Table 1. Success Rates of various Regimens of Second Trimester Termination

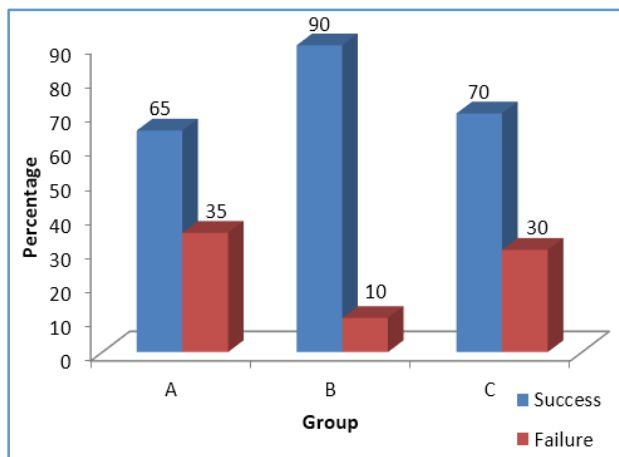


Figure 4. Success Rates of various Regimens of Second Trimester Termination

In the study by Grimes et al, they could not establish superiority with lowered dosing regimens of misoprostol. In their study, the dosage of mifepristone used was 200 mg which was lower than 600 mg in our study.⁽⁹⁾

Kulkarni et al on comparing various dosing regimens noted better success when mifepristone 600 mg was utilised and misoprostol was given after 4 hrs. between dosages of 200 – 400 µg.^(10,11)

In our study, only one case (1.7%) required blood transfusion in view of pre-existing anaemia and previous thrombocytopenia. 2 cases of MTP with mifepristone 600 mg and misoprostol 800 µg required dilatation and curettage procedure.

In the study of Dalve et al increased risk of haemorrhage and perforation were noted with failed medical abortion requiring surgical evacuation as opposed to primary surgical evacuation. Among the study population, 16 cases (26%) were previous caesarean section cases.

No complications and side effects were noted in the follow-up of the patients.

Majority of (89%) second trimester abortions were for anomalous babies or life-threatening malformations, whereas remainder (11%) constituted pregnancy out of medico-legal conditions requiring termination.

In the study of Schaff et al, a prevalence of similar indications for MTP were noted.⁽¹²⁾

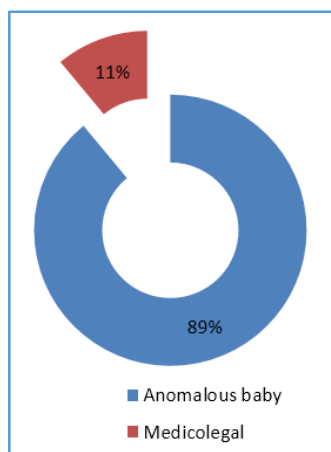


Figure 5. Indication for Second Trimester Termination

Grossman et al in their study also noticed, they had a higher prevalence of neural tube defects followed by cardiovascular defects and abdominal wall defects.⁽¹³⁾

Most common anomalies that led to second trimester termination of pregnancy in our study were hydrops (21%), anencephaly (18%), other neural tube defects (14%) and meningomyelocele (10%).

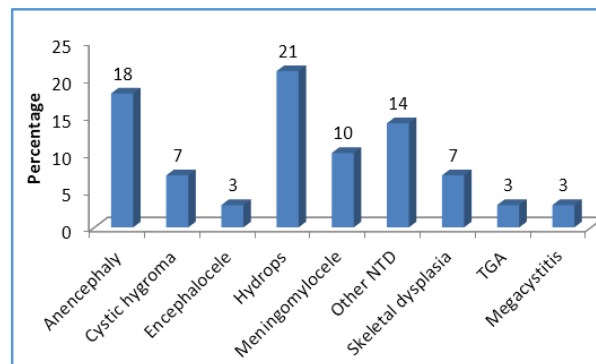


Figure 6. Various Anomalies leading to Second Trimester MTP

DISCUSSION

Out of 60 women, majority (42%) were 20 – 25 years’ age group and 60% were multiparous. Majority of terminations were for anomalous babies. Commonest anomaly was neural tube defect, same dose was kept for previous cases also. Only one case required blood transfusion, which is a case of thrombocytopenia.

CONCLUSION

600 mg mifepristone followed by 600 µg misoprostol had an induction expulsion interval < 24 hrs. and is equally efficacious when compared to higher doses of misoprostol (800 mg).

This regimen was found to be safe in cases of previous caesarean section with an efficacy of 100%.

In comparison with FIGO 2017 misoprostol recommendations, we found that a lower and less vigorous dosage regimen of mifepristone and misoprostol is efficacious in achieving second trimester MTP.

Limitations of the Study

Short study period, hence future pregnancy outcome or any long-term complications could not be assessed. Small study population.

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